Incidence and characteristics of adverse events in paediatric inpatient care: a protocol for a systematic review and meta-analyses

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INTRODUCTION

Adverse events (AEs) seriously affect quality of care and patient safety and has been recognized as a critical global healthcare issue [1] [2]. An AE may be defined as harm or disease, as well as death, caused by healthcare related to index admission, that was not an inevitable consequence of the patient's underlying condition [3]. Hospitalized children are fragile patient group and the space for inadequate or delayed care activities is narrow. Even a low degree of errors or omissions can affect the child's health and in long-term risk to affect the child's development and future [4].

There are various methods for detecting, measuring, and characterizing AEs in healthcare [5]. Retrospective record review using different methodologies, for example the Harvard Medical Practice Study method [6, 7] or the Global Trigger Tool [3], with subsequent adaptations (Trigger Tools) for different contexts, are commonly used methods for this purpose. Retrospective record review has been proven to be superior in comparison with most other methods, such as different kind of incident reporting systems or patient safety indicators, to detect AEs [8-10].

Rational

In adult care, several systematic reviews [11-14] regarding AEs identified using different kind of retrospective record review methods, with or without meta-analyses, have been published. Within paediatric care, to our best knowledge, only one systematic review exists which showed a pooled AE incidence of 2.0% [15]. This review included nine publications with a minimum of 1,000 patients and all, except one, had an admission year for the included patients ranging from 1984 to 2001. There is a need to systematically collect and analyse data about AEs within paediatric inpatient care, irrespectively of study sample sizes. Therefore, in this systematic review no limitation in sample size will be applied. Furthermore, an update of studies is also needed since the publication of Global Trigger Tool studies in recent years are extensive.

Aim

The aim of this systematic review is to report incidence and characteristics of AEs, in paediatric inpatient care, detected through Global Trigger Tool, Trigger Tool or Harvard Medical Practice Study methodology.

METHODS

The review is planned to be carried out as a systematic review and meta-analyses.

Eligibility criteria

The inclusion and exclusion criteria for publications are shown in table 1.

Table 1. Eligibility criteria in a hierarchical order

	Inclusion	Exclusion
Population	Children, all age groups, if they have been cared for at a paediatric inpatient unit Studies addressing both adults and children will be included if data provided for children are reported separately	Studies reporting adverse events (harm) for children with a specific disease, diagnose, for example, rheumatoid arthritis or children undergoing specific treatments or procedures as intubation, x-ray as well as only deceased patients
Context	Hospitalized patients, acute care settings, both acute and elective admissions All levels of inpatient care All types of specialties	Primary care, psychiatric care, day care/ambulatory care Emergency departments or other outpatient units at the hospital
Types of evidence source	Peer reviewed full text primary studies, reporting relevant quantitative outcome data Applied manual retrospective medical record review using Global Trigger Tool, Trigger Tool or Harvard Medical Practice Study methodologies as data collection methods No restriction in language No restriction in publication years	Study protocols with no AE outcome published Conference abstracts and editorials Systematic reviews Studies using, for example, clinical incident reporting systems as the primary data source and later these incident reports are analyzed using record review
Concept	All studies irrespective of which adverse event definition is used	Studies reporting only specific adverse events, for example, adverse drug event

Information sources

To identify relevant evidence for a review, it is advised to use more than one database. The search was performed using the following electronic databases: MEDLINE, Embase, Web of Science and Google Scholar according to Bramer and colleagues [16].

Search strategy

A search strategy was developed containing subject headings and free text words that describe the population, the context, the concept, and type of evidence source (table 1). These was assembled in search blocks and combined with the Boolean operator AND. Subject headings and free text words within the search blocks was combined with the operator OR and truncated where needed. The search strategy for MEDLINE is displayed in table 2.

Table 2. *S*earch blocks for MEDLINE

Concept
exp Iatrogenic Disease/, exp Medical Errors/, Patient Harm, adverse event*.tw., harm.tw, trigger*.tw.
AND
Population
exp Adolescent/, exp Child/, exp Infant/, p?ediatric*.tw., neonat*.tw., child*.tw., newborn*.tw., infant*.tw., adolescen*.tw., premature*.tw., preschool.tw., teenager*.tw.
AND
Context
exp Hospitals/, exp Inpatients/, exp Hospitalization/, exp Hospital Units/, exp Hospital Departments, hospital*.tw., intensive care.tw., inpatient*.tw.
AND
Type of evidence source
(review* ADJ5 (record* OR chart*)).tw., trigger tool.tw., Harvard Medical Pratice*.tw.

Selection process

Duplicates will be excluded in accordance with Bramer and colleagues [17] de-duplication description for EndNote, recommended when searching multiple databases with overlapping content. In the first step of screening, two pair of reviewers will independently, within and between the pairs, apply the eligibility criteria to the title and abstract, which reduces the risk of errors. Full texts will thereafter be retrieved for the titles and abstracts meeting the eligibility criteria. These full text publications will be assessed for eligibility criteria and publications that do not meet them will be excluded with reason for exclusion noted. A scan of the reference lists of studies included in the synthesis as well as personal libraries will be carried out to identify any additional publications.

Data collection process

To ensure high-quality data entry, data will independently be extracted by two researchers. Where co-authors' studies will be considered, no directly involved researchers will review those studies. The findings will be sorted and categorized in a data extraction template that will be constructed in Microsoft Excel.

Risk of bias assessment

To assess the risk of bias and applicability-related concerns for the respective included publication we will use a revised quality assessment tool (QAT). This QAT will be inspired by the Quality Assessment Tool for Diagnostic Accuracy Studies 2 (QUADAS-2) tool and by the QATs of Musy et al. [18] and Eggenschwiler et al. [19].

Primary outcome

A meta-analysis will be carried out with a primary outcome measure of AEs per 100 admissions ((number of AEs / number of admissions) * 100). We would have preferred to use AEs per 1,000 inpatient days as the primary outcome but this data is often not reported.

Secondary outcomes

We will also include secondary outcomes such as AEs per 1,000 inpatient days ((number of AEs / number of inpatient days) * 1,000), the percentage of admissions with one or more AEs (number of admissions with ≥1 AE / number of admissions) and percentage of preventable AEs (number of preventable AEs / number of AEs) as well as severity and other characteristics of AEs.

Statistical analysis

We will determine the number of AEs per 100 admissions and the number of AEs per 1,000 patient days from the reported data. Summary estimates for AEs per 100 admissions will be derived using a random effects logistic regression approach within the R metaprop function, choosing the Wilson method to derive confidence intervals. A random effects Poisson regression model will be used to obtain summary estimates and confidence intervals for the outcomes expressed as AEs per 1,000 patient days.

Meta-analyses will be divided according to the used AE definition, follow-up period or if more than one AE per patient is included. Sub-groups analyses will be carried out regarding severity and preventability.

Conflicts of interest

None.

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